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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,597	02/04/2004	James D. Ralph	SPINE 3.0-447 CONT	3441
51640	7590	10/09/2007		
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER HOFFMAN, MARY C	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,597	Applicant(s) RALPH ET AL.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al. (U.S. Patent No. 5,122,130).

Keller discloses an instrument (FIGS. 7-9) for holding an intervertebral spacer, the instrument comprising a shaft having a proximal end (top portion of instrument, see around ref. #26 in FIG. 7) forming a handle, and a distal end forming a claw subassembly (bottom portion); the claw subassembly including a first pincer (ref. #24) which is fixed at the distal end of the shaft and a second pincer (ref. #25) which is pivotally coupled with the first pincer for rotating into and out of spacer holding association with the first pincer; and an actuation mechanism (ref. #28) for selectively rotating the second pincer, wherein the first and second pincers have opposing inner curved surfaces that extend to a distal end of the instrument. The second pincer is spring biased away from the first pincer. The actuation mechanism comprises a sliding member mounted to the shaft which is selectively moveable in the distal direction by a force sufficient to overcome the bias of the spring, the distally directed movement of the sliding member thereby causing the second pincer to pivot toward the fixed first pincer,

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and the subsequent retraction of the sliding member in a proximal direction causes the sliding member to disengage the second pincer and the permits the pincers to separate under the bias of the spring. The second pincer includes a tapered surface, which is engaged by a corresponding surface of the sliding member, the engagement causes the second pincer to rotate relative to the first pincer. The first of the pair of pincers is fixed and a second being coupled to the first in open-biased opposition thereto, the first and second pincers having opposing inner curved surfaces that extend to a distal end of the instrument; and a sliding element translatable into and out of engagement with the second pincer to close and open the pair of pincers, respectively. The pair of pincers define an intervertebral spacer grasping enclosure having an access opening through which the intervertebral spacer can be passed for placement into the enclosure when the sliding element is out of engagement with the second pincer; and the spacer is securely maintained between the first and second pincers when the sliding element has been translated into engagement with the second pincer. The first and second pincers are mounted at the distal end of a common shaft, and the sliding element is translatable along the shaft; and wherein the second pincer has a portion thereof which is engaged by the sliding element to are close the pair of pincers. The second pincer is mounted to the common shaft by a pivot joint (see slot separating pincers ref. #24 and #25), and the portion of the second pincer which is engaged by the sliding element is a tapered surface, the angle of which tapered surface, when engaged by the sliding element, causes the second pincer to rotate about the pivot joint, closing the first and second pincers. The reference further discloses an intervertebral spacer (see FIG. 1)

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comprising a cylindrical member having an annular groove defining a central axial core portion and a pair of flange portions at opposing ends thereof; and the claw subassembly engages the spacer at the central axial core.

Claims 1 and 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Koch (U.S. Patent No. 640,308).

Koch discloses an instrument for holding an intervertebral spacer, the instrument comprising a shaft having a proximal end forming a handle (A), and a distal end forming a claw subassembly; the claw subassembly including a first pincer (B) which is fixed at the distal end of the shaft and a second pincer (C) which is pivotally coupled with the first pincer for rotating into and out of spacer holding association with the first pincer; and an actuation mechanism (I) for selectively rotating the second pincer, wherein the first and second pincers have opposing inner curved surfaces that extend to a distal-most end of the instrument. A sliding element (g) is translatable into and out of engagement with the second pincer to close and open the pair of pincers, respectively. The pair of pincers define a grasping enclosure having an access opening through which an intervertebral spacer is capable of being passed for placement into the intervertebral spacer grasping enclosure when the sliding element is out of engagement with the second pincer and is securely maintained between the first and second pincers when the sliding element has been translated into engagement with the second pincer. The first and second pincers are mounted at the distal end of a common shaft, and the sliding element is translatable along the shaft and wherein the second pincer has a portion thereof (d) which is engageable by the sliding element to close the pair of

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pincers. The second pincer is mounted to the common shaft by a pivot joint pin (e), and the portion of the second pincer which is engaged by the sliding element is a tapered surface, the angle of which tapered surface, when engaged by the sliding element causes the second pincer to rotate about the pivot joint pin, closing the first and second pincers. A pin (e) extends through the first and second pincers for pivotally coupling the first and second pincers.

Applicant is reminded that with regard to statements of intended use and other functional statements, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). See also *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Response to Arguments

Applicant's arguments filed 07/16/2007 have been fully considered but they are not persuasive.

Applicant's arguments regarding the Keller reference are not persuasive. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically

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pointing out how the language of the claims patentably distinguishes them from the references. In response to applicant's argument on page 5, 4th paragraph, and page 6, 1st paragraph, regarding the Keller patent, it is noted that the argument merely states what limitations the claims require by repeating the claim limitations in the argument and then stating the conclusion that the prior art does not disclose those limitations. Rule 37 CFR 1.111(b) requires that applicant MUST "distinctly and specifically point out errors" in the examiner's action. Also, arguments or conclusions of the attorney cannot take the place of evidence. *In re Cole*, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); *In re Schulze*, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); *Meitzner v. Mindick*, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

Also, in response to applicant's amendments, new ground(s) of rejection have been presented in this rejection.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER

